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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000
20582	7590	09/20/2007		
JONES DAY 222 East 41st Street New York, NY 10017-6702			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 09/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/528,989	Applicant(s) VOGEL ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,8,11-20,52,53 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11-20,52,53 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicant's remarks submitted June 19, 2007 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 7, 8, 11-20 and 52, ~~and 56~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al.
3. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection into tissue. The particles are made of hydrophilic acrylic co-polymer, and in preferred embodiment, with about 10% of bifunctional monomer. The particle sizes are range from 10 μm to 2000 μm . specific ranges of particle size within the range of 10 μm to 2000 μm are disclosed. See, particularly, the examples 1-21. The particles may be incorporated with other agents, such as dye, magnetic resonance imaging agent, or contrasting agent. The particles may also carry cell adhesion promoter. See, columns 3, lines 16-36, and the claims.
4. Boschetti et al. do not expressly disclose the polymer is anionic polymer, and the particular functions as herein recited. Boschetti also fails to expressly disclose the composition would be injectable through needles of about 26 to 18 gauge, or the particular amount of the particles in the composition, or the other particular agents in the composition as recited herein.

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However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use anionic polymer as the hydrophilic polymer, such as polyacrylic acid salt, and to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method.

5. A person of ordinary skill in the art would have been motivated to use anionic polymer as the hydrophilic polymer, such as polyacrylic acid salt, and adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method because it is disclosed that the composition should be injectable and acrylic polymer are known to be useful in the application. Anionic acrylic polymers are one of the three subgenus within the genus of acrylic polymers (the other two are neutral and cationic). It is noted that Boschetti et al. prefer neutral or cationic polymers (col. 2, lines 11-16), but claim 1 encompasses all hydrophilic acrylic copolymers. It is well-settled that “Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).” Note Further, employment of suitable carrier for an injectable composition, such as saline solution, would have been obvious to one of ordinary skill in the art because saline is a well-known biocompatible carrier. Further, the incorporation of other well-known therapeutical agents, such as anti-inflammatory agents, or cells, with the particle would have been obvious since the other agents are known to be useful as therapeutical agents. As to the functional limitations, such as “swellable,” “wherein the polymer can increase its weight by at least about 20 times its original dry weight upon contacting water”, the examiner notes that since the reference teaches, or suggests all the limitations other than the functional properties, the polymer composition as

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suggested by the reference would reasonably be expected to have the same properties as herein claimed. When the reference discloses all the limitations of a claim except a property or function, *the burden is shifted to applicant* for proof that the subject matter as taught or suggested by the reference does not possess the function herein claimed. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

6. Claims 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al. for reasons discussed above, and further in view of Tahara et al. (U.S. 5,298,570).

7. Boschetti et al. does not teach expressly the employment of sodium acrylate, and vinyl alcohol copolymers as the hydrophilic acrylic polymer.

8. Tahara et al. teach sodium acrylate/vinyl alcohol co-polymers are known hydrophilic biodegradable polymer. See, particularly, the example 6 in column 6 and the claims.

9. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer.

A person of ordinary skill in the art would have been motivated to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer because hydrophilic acrylic polymers are generally known to be useful, and sodium acrylate vinyl alcohol copolymers is particularly known as hydrophilic polymer. The employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

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Response to the Arguments

Applicants' remarks submitted June 19, 2007 have been fully considered, but are not persuasive.

For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR Int'l v. Teleflex Inc., 82 USPQ2d 1385, 1395 (2007).

Claim 1 of Boschetti et al. states:

1. A microsphere, having a diameter ranging between about 10 to about 2000 μm , useful for embolization which comprises a *hydrophilic acrylic copolymer* coated with a cell adhesion promoter and a marking agent. (emphasis added).

As generally understood by one of ordinary skill in the art, hydrophilic acrylic copolymers (or polymer) are composed by three group, anionic, cationic, and non-ionic or neutral. Therefore, no explicit teaching is necessary to have led the skilled worker to the particular components – hydrophilic anionic acrylic polymer - recited in claims because it was known in the prior art as a hydrophilic acrylic polymer, prompting the skilled worker to have combined them.

The legal conclusion of unpatentability for obviousness depends on four factual inquiries identified by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). These inquiries concern: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness. Against this background, the obviousness or nonobviousness of the subject matter is determined. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1388 (2007).

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“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.** In that instance the fact that a combination was obvious to try might show it was obvious under section 103.” In the instant case, since it is known hydrophilic acrylic copolymers are known to be useful and hydrophilic acrylic copolymers only have three subgenres, the employment of any one of the subgenus would have been obvious to one of ordinary skill in the art.

Applicants have argue that the cited prior arts do not teach or suggest the limitation of “injectable” and “swellable” as recited in the claims, but fails to point out how and why the composition as suggested by the cited prior art cannot possess the recited propertis or function. Particularly, the cited reference teaches the particle size may be in the range of 10 μm to 2000 μm . There is no reason why a liquid suspension of small size particles, e.g., 50 μm cannot be injectable through an 18 guage needle (with inner diameter of more than 800 μm). Further, swellable is understood as a common property of crosslinked hydrophilic polymer or copolymer. Applicants fails to point out why and how such properties is not obvious to one of ordinary skill in the art and is not present in well known crosslinked sodium polyacrylate as suggested by the cited prior art.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

